

Keshma KOTIAN *et al.*,
Serial No. 10/768,348
"Stabilized Paroxetine Formulation"

IN THE SPECIFICATION

At page 11, line 6, please add the following new paragraphs:

5 We accordingly here disclose and claim a new moisture barrier pharmaceutical
excipient solution comprising: A) ethylcellulose; B) polar solvent; C) alcohol; and D) a
surfactant. An example of a suitable surfactant is polysorbate 80. The surfactant (e.g.,
10 polysorbate 80) and the ethylcellulose can be present in a ratio of approximately 1.00 :
0.165.

We also disclose and claim a new process for manufacturing a substantially
moisture stable pharmaceutical product, comprising: A) mixing ethylcellulose, polar
solvent, alcohol and a surfactant to make a moisture barrier pharmaceutical excipient
15 solution; B) mixing a drug substance with said moisture barrier pharmaceutical excipient
solution to form substantially moisture stable drug substance; and C) coating the
substantially moisture-resistant drug substance of step B in a pharmaceutically-acceptable
coating. The pharmaceutically-acceptable coating may include a gelatin capsule, the
surfactant may include polysorbate 80, and the surfactant (e.g., polysorbate 80) and the
ethylcellulose may be present in a ratio of approximately 1.00 : 0.165. The drug
20 substance may include paroxetine. Alternatively, the surfactant includes polysorbate 80,
and the polysorbate 80 and the ethylcellulose are present in a ratio of approximately 1.00
: 0.165, and the drug substance includes paroxetine.

We also disclose and claim a substantially moisture stable drug product
comprising: A) A substantially moisture stable core including a drug substance,
ethylcellulose and a surfactant; and B) An outer layer surrounding said core, said outer
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layer including a pharmaceutically acceptable material, the outer layer substantially free of the drug substance. The surfactant may include polysorbate 80, and the polysorbate 80 and said ethylcellulose may be present in a ratio of approximately 1.00 : 0.165. The drug substance may include paroxetine. Alternatively, the drug substance includes paroxetine, said surfactant includes polysorbate 80, and the polysorbate 80 and ethylcellulose are present in a ratio of approximately 1.00 : 0.165.

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